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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,715	03/08/2002	Steven J. Catani	15117.0091	7318
23767	7590	03/23/2004		
PRESTON GATES ELLIS & ROUVELAS MEEDS LLP 1735 NEW YORK AVENUE, NW, SUITE 500 WASHINGTON, DC 20006				
			EXAMINER KRISHNAN, GANAPATHY	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/092,715	CATANI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ganapathy Krishnan	1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5,7-10 and 12-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-48 is/are allowed.
- 6) ☒ Claim(s) 5 and 7-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

The amendment filed January 13, 2004 has been received, entered into the record and carefully considered. The following information provided affects the application:

1. Claims 1-4, 6, 11 and 49-54 have been cancelled.
2. Claims 5, 7-9 and 12 have been amended.
3. Remarks drawn to 102(e), claim objection to allowable claims.

Claims 5, 7-10, 12-48 are pending.

The finality of the previous office action has been withdrawn and the following new rejections are made of record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 102***

The rejections of claims 1-4, 6 and 11 have been rendered moot by cancellation of the claims. The following rejections are made of record.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 7-10 rejected under 35 U.S.C. 102(b) as being anticipated by Navia et al (US 5498709).

Claims 5, 7-10 are drawn to removal of impurities from a composition including sucralose and first and second impurities with first and second solvents having partial

Art Unit: 1623

immiscibility, wherein the second solvent could be ethyl acetate (claim 7) and specific ratios of solvents and recovering sucralose via crystallization.

Navia et al teach the extraction of sucralose in an aqueous-brine solvent (first solvent) with impurities and extracting it with ethyl acetate (second solvent) to transfer impurities into the second solvent and then back-extract the ethyl acetate extracts with water (third solvent) to transfer the sucralose in to the water and retaining the second impurities in the first solvent (col. 10, lines 15-25; col. 6, lines 35-67). The sucralose is finally recovered by crystallization (col. 6, line 67). This is seen to meet the limitations of instant claims 5, 7, 9 and 10. It is well within the purview of one of ordinary skill in the art to adjust the ratios of solvents used to optimize the extraction process.

Regarding Claim 8, Navia et al teach the reaction mixture is initially in DMF (first solvent). This is then steam stripped to remove DMF. This step is seen as an extraction with a second solvent wherein some of the impurities will also be transferred out of the mixture. The crude sucralose is then extracted with ethyl acetate to transfer the sucralose in to the organic phase (sucralose transferred to the third solvent-ethyl acetate) while some second impurities are retained in the first solvent (see col. 10, lines 5-20). This teaching of Navia is seen to meet the limitation of claim 8.

### ***Conclusion***

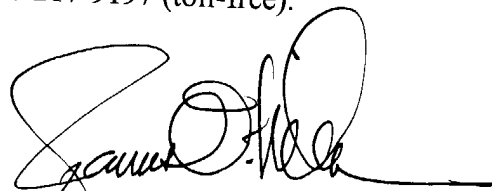
1. Claims 5 and 7-10 are rejected.
2. Claims 12-48 drawn methods of extraction of sucralose as instantly claimed are neither taught or fairly suggested by the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



JAMES O. WILSON  
SENIOR PATENT EXAMINER  
ART UNIT 1623